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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/509,612	03/29/00	ABRIGNANI S	0366.103

027476
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Intellectual Property - R440
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HM12/0509

EXAMINER	
WORTMAN,D	
ART UNIT	PAPER NUMBER
1648	10

DATE MAILED: 05/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/509,612	Abrignani et al.
Examiner	**Art Unit**
Donna C. Wortman, Ph.D.	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Apr 19, 2001

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-26 is/are pending in the applica

4a) Of the above, claim(s) 1-6, 7 in part, and 8-26 is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 7 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Applicant's election with traverse of Group III, claim 7, insofar as it reads on treatment using CD81, in Paper No. 10 is acknowledged. The traversal is on the ground(s) that Applicant contends that it is unclear how claims 8, 10 and 11 could be included in both Groups I and II and how claim 7 can be included in both claims III and IV; Applicant has queried whether a requirement for election of species was intended. Applicant's traverse has been considered but not found persuasive. A requirement for restriction to one of the seven inventions as set forth in the previous action was indeed what was intended, and not a requirement for election of species. Applicant's contention that "It is impossible for claims 8, 10 and 11 to be 'patentably distinct' from themselves" is not understood since no basis for that contention was given; is it Applicant's intention to concede that any prior art that applies to CD81 will be sufficient to render obvious any compound that binds CD81? It remains the Examiner's position claims 7, 8, 10 and 11 as filed recited, in the alternative, treatment methods and compositions that are in fact patentably distinct as set forth in the previous action. CD81 protein is patentably distinct from a compound that binds to CD81, since the two products are structurally different; a method of treatment using CD81 is patentably distinct from a method of treatment using a compound that binds CD81 since the two methods necessarily require the use of structurally different products.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6; 7 in part, i.e., insofar as claim 7 is drawn to a method of treatment using a compound that binds to CD81; and 8-26 are

withdrawn from consideration as drawn to non-elected inventions. Claim 7, insofar as it reads on treatment using CD81 and functional equivalent thereof, is presently under examination.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite in reciting two patentably distinct inventions in the alternative, i.e., it effectively recites an improper Markush group.

Claim 7 is indefinite because it fails to particularly point out and distinctly claim the subject matter which is the elected invention. Amendment of the claim to delete the non-elected subject matter would overcome this rejection.

Claim 7 is indefinite because it recites "a CD81 protein or a functional equivalent thereof." CD81, also known as TAPA-1, is found in many types of cells and is highly conserved across species. In B cells, for example, CD81 is involved in activation and proliferation (see, e.g., Rice, cited on PTO 892, attached). In the absence of additional limiting language, it is unclear what CD81 equivalent function is being claimed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 7 is drawn to the pharmaceutical use of CD81 or functional equivalent thereof to reduce viral infectivity and encompasses human treatment using the protein or some undefined functional equivalent. The specification does not teach that administration of the CD81 protein or any portion of it, or any compound that in some sense functions in the same way as CD81, in fact is of any therapeutic value to a human subject in reducing viral infectivity. The instant specification at page 4 speculates that the protein or its functional equivalent may have a therapeutic effect. Rice (Hepatology 29:990-992, 1999, cited on PTO 892) points out that merely blocking or preventing HCV E2-CD81 interaction may or may not be of therapeutic value. (See, e.g., Rice, paragraph bridging pages 990-991). Petracca et al. (Journal of Virology 74(10):4824-4830, 2000, cited on PTO 892, attached) disclose that internalization of ligands by CD81 is rather inefficient and that it appears certain hepatoma lines bind HCV in the absence of CD81,

illustrating that mere knowledge of the association of CD81 and HCV is not sufficient to support predictability in treating HCV infection by administering CD81 or a functional equivalent thereof. One of skill in the art requires more than speculation and indeed requires some factual evidence that a beneficial effect in the form of reducing viral infectivity is actually obtained by administration to a human of the CD81 protein or a functional equivalent of CD81. In the absence of any such factual evidence, the specification cannot be said to enable one skilled in the art to use the invention as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Wortman whose telephone number is (703) 308-1032. The examiner can normally be reached on Monday through Thursday from 7:30 am to 5:00 pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Donna Wortman, Art Unit 1648, and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1648 FAX telephone number for official papers is (703) 308-4242. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday, or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Donna C. Wortman, Ph.D.
Primary Examiner

May 8, 2001